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(54) **An evacuation device for sterile containers**

(57) A container for a sterile fluid, such as blood, infusion or nutrient solution or cleaning fluid, normally includes a filler device for the supply of fluid into the container and a tubular evacuation device (3) for enabling discharge of the fluid from the container upon penetration thereof by a connection device shown in part at (45). The evacuation device includes a self-sealing sealing diaphragm (23) of an elastic material. A first cylindrical space (32) is provided and is arranged to accommodate the connection device (45) in sealing surface contact with the evacuation device, and a second space (21), enlarged in relation to the first space, is disposed between the first space (32) and the sealing diaphragm (23). The elastic self-sealing sealing diaphragm (23) is arranged to bend inwardly into the enlarged space (21) when pressure is applied thereto by the connection device. When the connection device is removed, the diaphragm (23) self-seals to preserve the sterility of the contents of the container. Protective diaphragms (14) and (17) are also provided.

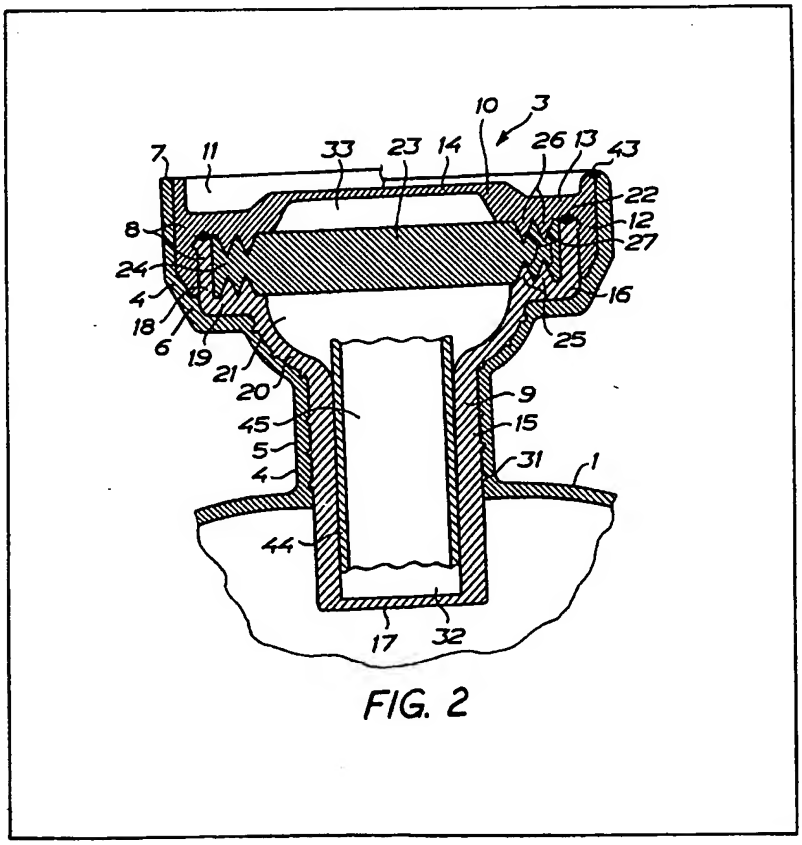

FIG. 2

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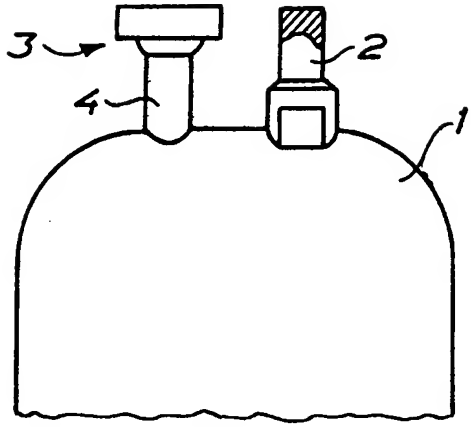

FIG. 1

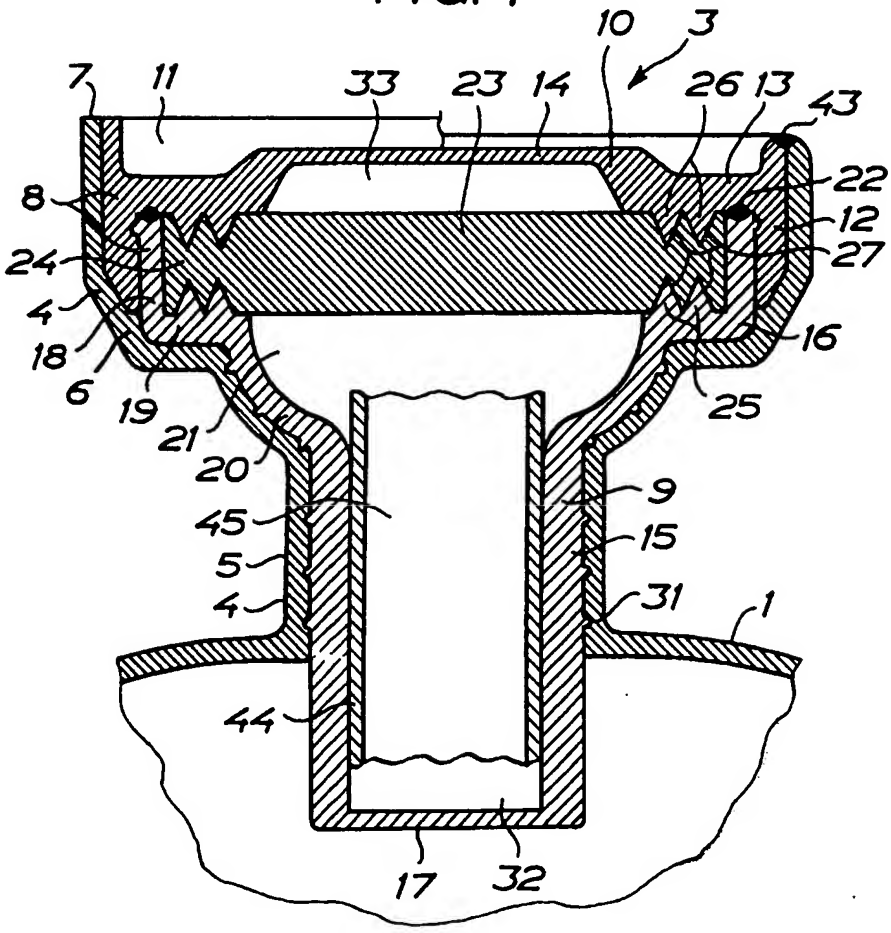

FIG. 2

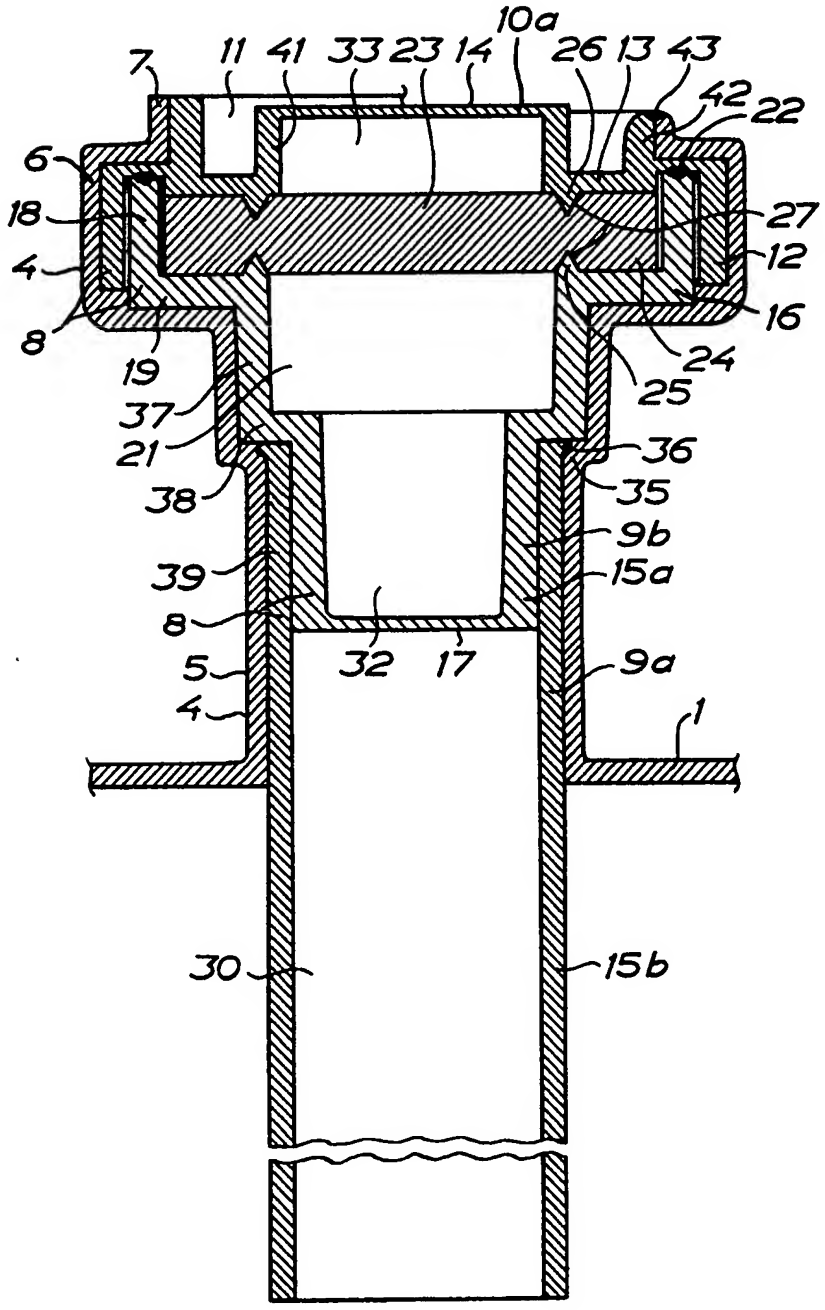
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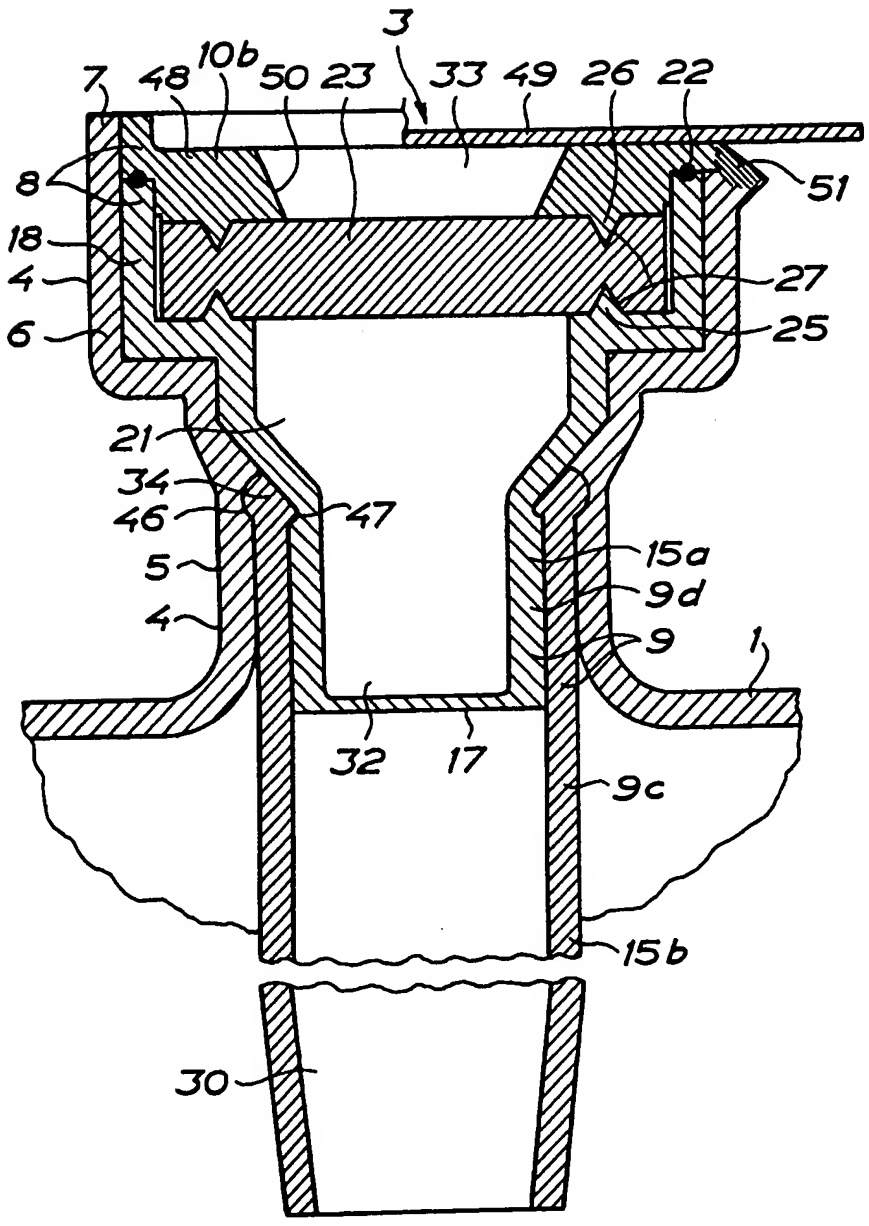
FIG. 3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15a
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9c
15b
30

FIG. 4a

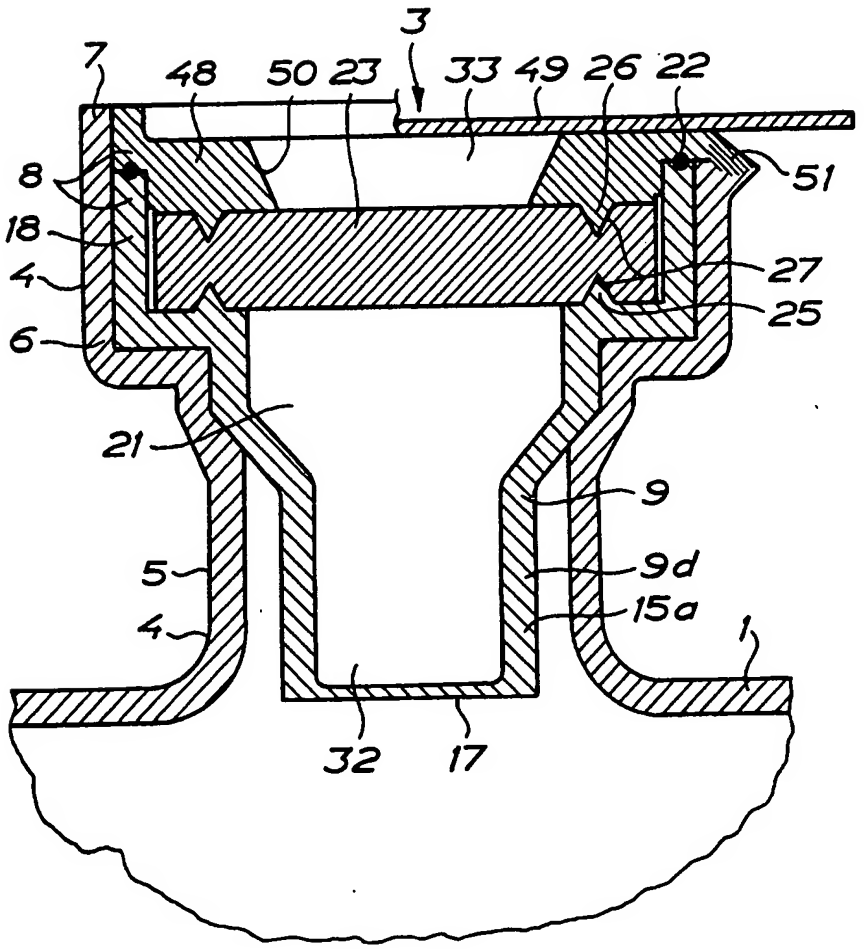

FIG. 4b

SPECIFICATION

An evacuation device for sterile containers

The present invention relates to an evacuation device for a container arranged to enable discharge of the contents of the container upon penetration thereof by a connection device. Such an evacuation device is intended for use with a container whose contents must be kept sterile, for example, for a container for a fluid such as blood, infusion or nutrient solution, or cleaning fluid.

Infusion containers having an evacuation device shaped like an outlet pipe and fitted with a detachable end section are known. When the container is connected to a drip chamber, a connection device is fitted in the outlet pipe after the end section has been broken off. During the time which elapses between the breaking off of the end section and the fitting of the connection device the container is open so that its sterility is lost. Moreover, the connection device cannot be removed and replaced for continued treatment, should this be required, since sterility cannot be maintained and after the removal of the connection device the contents of the container risk further contamination.

It is an object of the present invention to provide an evacuation device in which the drawbacks outlined above are overcome.

According to the present invention there is provided an evacuation device for a container arranged to enable discharge of the contents of the container upon penetration thereof by a connection device, wherein said evacuation device comprises at least one self-sealing sealing diaphragm of an elastic material, a first space for the accommodation of a connection device during discharge, and a second space, enlarged in relation to the first space, and disposed between the first space and the sealing diaphragm, the sealing diaphragm being arranged to bend inwardly into said second enlarged space under the influence of pressure applied by the connection device.

In a preferred embodiment of the invention the evacuation device comprises an insert which encloses said sealing diaphragm and which in addition also comprises an outer protective diaphragm and an inner protective diaphragm each disposed on either side of and at a distance from the sealing diaphragm.

In another preferred embodiment the outer protective diaphragm is produced as a removable attached diaphragm in order to enable, where required, disinfection of the outer limiting surface of the sealing diaphragm prior to penetration of the sealing diaphragm by the connection device.

In some embodiments the sealing diaphragm is produced in a slitted form in order to facilitate penetration of the diaphragm by the connection device. This also minimises the risk of particles being released from the diaphragm when the connection device is moved through it, since the connection device does not need to cut its way through the material of which the diaphragm is made.

Evacuation devices of the invention enable a closed system for the fluid in the container to be maintained during the fitting of the connection device and after the connection device has been removed. By this means it is possible to interrupt discharge from the container and to resume it at a later time. Devices of the invention also make it possible to keep the container in a stand-by position without loss of fluid, i.e. with the evacuation device facing downwards to await the resumption of treatment.

Embodiments of the present invention will hereinafter be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1 shows one end portion of a container having an evacuation device,

Fig. 2 shows a longitudinal section of a first embodiment of an evacuation device; an insert of the evacuation device being illustrated on the left hand side prior to welding, and on the right hand side after it has been welded to an outlet section,

Fig. 3 shows a longitudinal section of a second embodiment of an evacuation device, an insert of the evacuation device being illustrated on the left hand side prior to welding, and on the right hand side after it has been welded to an outlet section,

Fig. 4a shows a longitudinal section through a fourth embodiment of an evacuation device having an upper surface which is accessible for disinfection, and

Fig. 4b shows a longitudinal section through a further embodiment of an evacuation device which similarly has an upper surface which is accessible for disinfection.

Throughout the description, the same reference numerals have been used to refer to identical or equivalent features of the device.

Fig. 1 shows one end portion of a flexible container body 1 which is produced of a suitable plastics material such as polyvinyl chloride, polypropylene, polyethylene, polyamide, polyethylene terephtalate or similar thermoplastics, or laminates formed from combinations of such materials. It is intended that the container be filled with a liquid such as blood, a nutrient or infusion solution, or a cleaning fluid. The container and its contents would be sterilised after the container had been filled, and it is also intended that the container be disposed of once its contents had been used.

In known manner the container is provided with a filler device 2 by means of which the initially flattened or compressed container is filled. In addition, the container has an evacuation device 3 by means of which the contents of the container can be discharged in a sterile manner.

The evacuation device 3 comprises a tube-shaped outlet section 4, herein after referred to as an outlet pipe. In all the illustrated embodiments, the outlet pipe 4 has a narrow portion 5 closest to the container body 1 and an enlarged portion 6 furthest from the container body 1. The enlarged portion terminates in a mouthpiece edge 7. The evacuation device is formed in a single piece with the container body and is connected to the interior of the container body.

Fig. 2 illustrates a first embodiment of an evacuation device 3 of the invention. A tubular insert 8 arranged within the outlet pipe 4 has an inner first section 9 and an outer second section 10. The second section 10 suitably possesses a circumferential, axially and outward-facing collar 11. The mouthpiece edge 7 is

disposed such that it can be joined to the collar 11 by a welded joint 43, and thereby finally ensure that the container is sealed in a sterile manner. The outer second section 10 also possesses a cylindrical wall 12 which is joined to a top wall 13 which in turn encloses an outer protective diaphragm 14. The said inner first section 9 comprises a tubular inner portion 15 and an enlarged outer portion 16. The inner portion 15 of the section 9 has an external diameter which substantially corresponds to the internal diameter of the narrow portion 5 of the outlet pipe 4 such that good frictional adjustment between the portions 15 and 5 is attained. In addition, the tubular inner portion 15 is sufficiently long that its free end extends into the interior of the container body a predetermined amount. This means that the residual quantity of air in the container and the volume of the fluid that remains in the container after its evacuation can be controlled.

An inner protective diaphragm 17 is disposed in the inner portion 15 at a predetermined distance from the diaphragm 14 of the outer insert section 10. The enlarged outer portion 16 of the inner insert section 9 has a predominantly cylindrical wall 18, a base wall 19, and a conical, concave intermediate wall 20 which is joined to the inner portion 15. The inner portion 15 thereby defines a first space 32 in the insert which gives way to an enlarged second space 21 which, inter alia, is delineated by said intermediate wall 20. The inner insert section 9 is disposed so as to be accommodated with its cylindrical wall 18 in the space which is enclosed by the cylindrical wall 12 of the outer insert section 10 so that these cylindrical walls have sealing surface contact with each other. The two inserts are welded together at a circumferential welding point 22 for formation of a hollow unit.

The insert 8 further comprises a circular self-sealing sealing diaphragm 23 of elastic material, e.g. of a suitable rubber or plastics material. Cooperating engagement devices 25 to 27 are disposed on edge portions 24 of the sealing diaphragm and on the two insert sections 9 and 10 for stable retention of the sealing diaphragm. The engagement devices 25 to 27 are arranged to fix the edge portions 24 of the diaphragm 23 against radial movements and to ensure that the diaphragm does not come away, either partially or completely, from the insert sections when pressure is applied to the centre portion of the sealing diaphragm 23 by means of a connection device. In the embodiment shown, the engagement devices comprise annular grooves 27 in opposite surfaces of the edge portion 24 of the sealing diaphragm and corresponding retaining rings 25 and 26 on the facing surfaces of the base wall 19 of the inner insert section 9 and of the top wall 13 of the outer insert section 10. During assembly the sealing diaphragm 23 is placed between the two insert sections such that the retaining rings 25 and 26 engage in said grooves and retaining rings, whereby the sealing diaphragm 23 is effectively clamped between the insert sections. Thereafter, a welding operation is carried out such that the sealing diaphragm is permanently enclosed in a sterile manner.

The inner elastic protective diaphragm 17 is relatively thin and protects the contents of the container against particle contamination, whilst the outer elastic protective diaphragm 14, which is also relatively thin, protects the inner sealing diaphragm 23 against bacterial contagion. The outer protective diaphragm 14 and the enclosed sealing diaphragm 23 together define a third space 33 in the insert, the diameter of the third space 33 being substantially the same as that of the second enlarged space 21.

Fig. 2 also shows a section of a connection device 45 which may, for example, be connected to a drip chamber (not shown). In Fig. 2 the connection device 45 has been inserted into the evacuation device. Reference number 44 indicates a preferably slightly conical section of the connection device. The section 44 has an external diameter that is as large as or larger than the internal diameter of the tubular portion 15. This means that the conical section 44 sealingly abuts the inner limiting surface of the inner portion 15. The section of the connection device shown constitutes solely an illustration of the aforementioned sealing abutment. Of course, with a connection device in the inserted position both the protective diaphragms 14 and 17 and the sealing diaphragm 23 would be pierced and moved aside by the connection device.

Fig. 3 shows an alternative embodiment of the invention in which the inner insert section 9 is made up of first and second cooperating elements 9a and 9b. The first elements 9 has a substantially cylindrical end area 39 closest to the sealing diaphragm 23, and this encloses a substantially cylindrical area 15a of the second element 9b which is located furthest away from the sealing diaphragm 23. The diameters of the cylindrical areas 39 and 15a are arranged to give a friction fit between the two elements 9a and 9b.

The first element 9a also has a tubular inner portion 15b which cooperates by means of good frictional adjustment with the narrow portion 5 of the outlet pipe 4 and extends into the interior of the container body 1. The narrow portion 5 of the outlet pipe 4 is provided with a flared projection 35 which is arranged to cooperate with a corresponding projection 36 in the end area 39 of the first element 9a to secure the position of the first element 9a in the outlet pipe. The second element 9b has a substantially cylindrical wall 37 which is connected both to the base wall 19 thereof and to a second base wall 38 which forms the transition for the cylindrical area 15a. The cylindrical area 15a is connected to the inner protective diaphragm 17 which defines a space 30 within the first element 9a and open to the interior of the container. The flared projection 35 in the outlet pipe 4 expands to an inner diameter exceeding the outer diameter of the end area 39 of the element 9a. Thus, the projection also forms a contact surface for the second base wall 38 of the second element and thereby contributes towards securing the position of the second element 9b in the outlet pipe 4. The wall portions 37 and 38 thus correspond to the intermediate wall 20 of the embodiment shown in Fig. 2. The disposition of the inner first section 9 as two separate linked elements facilitates the manufacture of the insert when the inner protective diaphragm 17 is to be located within the tubular inner portion 15 as is shown in Fig. 3.

The outer second section 10a of the insert 8 is in the embodiment shown in Fig. 3 disposed with its top wall 13 enclosed by an inner, generally cylindrical wall 41

and by an outer cylindrical wall 42. The inner cylindrical wall 41 connects the top wall 13 with the outer protective diaphragm 14, and the outer cylindrical wall 42 forms a contact and connection device for the mouthpiece edge 7 of the outlet pipe 4.

The construction of the outer second section 10a which is illustrated in Fig. 3 acts to stiffen the second section 10a such that the fixing of the sealing diaphragm 23 is reinforced. Another factor which contributes towards this is, as shown in the figure, the location of the retaining rings 25, 26 and the annular grooves 27 primarily in the area between the cylindrical wall 37 of the second element 9b and the inner wall 41 of the second section 10a.

In the embodiment of Fig. 3, the cylindrical surfaces of the cylindrical wall 18 of the enlarged outer portion 16 do not contact the adjacent surface of the sealing diaphragm 23 and the cylindrical wall 12 of the outer second section 10a. This embodiment can be selected in order to facilitate production since the sterility of the evacuation device is guaranteed by the welded joints 22 and 43, between the cylindrical wall 18 and the second section 10a and between the enlarged portion 6 of the outlet pipe and the second section 10a respectively.

Fig. 4a shows an embodiment of an evacuation device which is similar to that of Fig. 3 in that the inner insert section 9 is composed of a first element 9c cooperating with a second element 9d. The first element 9c of the inner insert section terminates at its upper end in a thicker edge portion 34 which is arranged to cooperate with respective grooves 46 and 47 formed in the narrow portion 5 of the outlet pipe 4 and in the second element 9d. The first element 9c is arranged to be fixed relative to the second element 9d and relative to the outlet pipe 4 respectively by means of the snap-action cooperation of the edge portion 34 and the grooves 46 and 47.

In the embodiment shown in Fig. 4a, the outer second section 10b of the tubular insert 8 is shaped as an annular attachment section 48 which abuts against the sealing diaphragm 23. In its central section the annular section 48 has an aperture exposing the upper surface of the sealing diaphragm 23. This aperture is defined by a conical surface 50 which provides a relatively gentle transition to the upper surface of the sealing diaphragm in order to facilitate the disinfection thereof and of the region thereabouts. The annular section 48 is further provided with a downwardly facing attachment ring 26 for cooperation with an upper annular groove 27 formed in the sealing diaphragm 23. The sealing diaphragm 23 is also fixed to the second element 9d of the inner insert section 9 by means of a lower groove 27 in the diaphragm and an upwardly facing attachment ring 25 in the upper surface of the second element 9d. The annular section 48 is joined to the mouthpiece edge 7 of the enlarged portion 6 of the outlet pipe 4 by means of a weld 51. An upper diaphragm 49 covers the aperture of the annular section 48 and is detachably mounted (e.g. glued or welded) on the annular section. The upper diaphragm 49 may have projecting portions suitable for use as gripping devices when the diaphragm is to be removed.

Fig. 4b shows an embodiment in which the design and shape of the inner insert section 9 is substantially the same as that of the second element 9d of the embodiment shown in Fig. 4a. Between the cylindrical region 15a of the inner insert section 9 and the narrow portion 5 of the outlet pipe 4 a free space is defined which makes it possible to match the internal diameter of the cylindrical region 15a with the external diameter of the connection device 45 to be inserted whilst retaining the shape and diameter of the narrow portion 5 of the outlet pipe. It will be realised that this enables a considerable rationalisation and reduction of the costs of production and stocking since the outlet pipe 4 can be made to a uniform design and size which is to a large extent independent of the internal diameter of the cylindrical region 15a. In some of the embodiments shown, the cylindrical region 15a extends into the container. In the embodiment shown in Fig. 4b the cylindrical region 15a is arranged to terminate next to the wall of the container 1. In fact, the length of the cylindrical region 15a is chosen in dependence upon the residual quantity of air and the volume of fluid that it is required to retain in the container after use.

The sealing diaphragm 23 is arranged to have sufficient elasticity such that it returns immediately to its flat initial position after it has been penetrated by a pointed connection device, and the connection device has subsequently been withdrawn from the insert. The elasticity of the sealing diaphragm is also sufficiently high and the plasticity of the material thereof is sufficiently great for the sealing diaphragm to conform itself in shape to and enclose the inserted connection device. This ensures that the diaphragm forms a seal around the connection device during the evacuation operation, such a seal being required primarily from the point of view of hygiene. In order to ensure the necessary resilience of the central portions of the diaphragm so that said flat initial position can be rapidly assumed after the connection device has been withdrawn from the insert. It is also important, that the sealing diaphragm has a minimum thickness of approximately 1.0 mm. Preferably, the sealing diaphragm has a thickness in the range 1.5 mm to 2.5 mm. These material thicknesses are related to presently proposed materials. If other materials are used they may, of course, make it possible or necessary for the sealing diaphragm to have different dimensions.

In order to prevent fluid leakage, a sealing connection is made between the connection device and the evacuation device 3. This sealing connection can be ensured as shown in Fig. 2 by providing the connection device 45 with the slightly conical section 44 which makes sealing contact with the inner surface of the tubular inner portion 15 or 15a. Alternatively, the inner surface of the inner portion 15 or 15a may be slightly conical, or both the surfaces may be suitably inclined.

To facilitate the penetration of the sealing diaphragm by the pointed connection device, the area of penetration of the diaphragm may be provided with one or several weakened zones, for example, by cuts or scores that penetrate the material wholly or partially. Thus, the weakened zones may comprise a single cut, or a series of intersecting cuts.

The enlarged space 21 of the inner insert section 9 is

of a sufficient size to enable the sealing diaphragm to bend freely into the spaceunder the effect of the pressure from the pointed connection device as the latter penetrates the sealing diaphragm. After penetration the resilient energy that is accumulated through the inward bending is released so that when the connection device is removed, an instantaneous return of the deflected central portion of the sealing diaphragm to a flat initial position is achieved so that perfect sealing is attained and guaranteed.

The embodiments shown in Figs. 4a and 4b are particularly designed for applications where fluid is removed from the container more than once. To prepare the container for use, the upper diaphragm 49 is torn off. In certain applications an additive is supplied to the fluid, e.g. by means of a hypodermic syringe which is inserted down through the sealing diaphragm and the inner protective diaphragm 17. Once the supply of additive is concluded, it is possible to re-disinfect the sealing diaphragm in conjunction with subsequent insertion of the connection device 45. It will be readily appreciated that repeated removal and insertion of the connection device and intervening supply of additive to the fluid can be easily performed, especially when using the embodiments shown in Fig. 4 whilst retaining the required sterility and cleanliness of the fluid. Previous techniques for providing containers of the kind treated here with special supply devices (additive gates) are simplified by the invention since the evacuation device can also be used for this purpose. In many applications this means both simplified handling and a cheaper container.

In order to increase the engagement between the insert 8 and the outlet pipe, the insert may be fitted with annular projections 31 which penetrate the wall of the outlet pipe as is shown in Fig. 2.

The insert is pre-sterilised and introduced into the outlet pipe 4 under hygienic conditions, after which the insert is welded to the outlet pipe at its mouthpiece edge. In some embodiments, the upper edges of the outlet pipe 4 and of the insert 8 have to be trimmed before the welding operation is performed. The welding of the two insert sections 9 and 10 is preferably undertaken by means of ultrasonics, whilst the welding of the insert and the outlet pipe maybe performed by any suitable method, for example, by thermal welding. The insert sections are preferably manufactured of the same plastics material as are the container and its outlet pipe.

The container may be provided with a separate diaphragm-sealedaperature for the introduction of various additives, for example for the addition of drugs and/or nutrients into an infusion solution. As a rule, the container is fitted with suspension devices (not shown) which are disposed in the end of the container facing away from the evacuation device 3 so that the container can be suspended during use. The filler device as well as the evacuation device can be protected by protective sleeves or similar devices in order to ensure complete hygiene, which protective sleeves are removed when the container is used.

During use the compressed container is filled with a required fluid via the filler device, after which it is sealed, preferably by welding and the filled container is sterilised. During evacuation a connection device is made to penetrate by means of its pointed end the three diaphragms of the evacuation device insert, after which fluid drainage is commenced. This drainage can be interrupted when required and the connection device withdrawn from the insert. It is possible to withdraw the connection device without fluid leaving the container, and, if the interruption is of short duration, without any loss of sterility. Subsequently, the connection device may be reinserted through the previously penetrated sealing device.

The invention is not limited to the embodiments described above, and variations thereof are possible. For example, the invention can be applied to non-compressible containers of plastics material or to containers of a different material, for example, of glass. In an alternative embodiment, the outlet pipe could have a substantially uniform inner diameter (without any expanded section) for the accommodation and welding into position therein of an insert consisting of several sections, the insert having an outer uniform diameter matched to the inner diameter of the outlet pipe. The inner insert section is provided with a through channel closest to the container for accommodating the pointed connection device, and an enlarged space for receiving the outwardly bent sealing diaphragm as in the previously described embodiments. Even if a self-sealing sealing diaphragm is normally sufficient to ensure the necessary hygiene between two evacuations, several, e.g. two, such sealing diaphragms can, if so required, be disposed after each other with intervening spaces and enlarged spaces which enable a required favourable outwards bending of each sealing diaphragm. The two sealing diaphragms are thus enclosed by inner and outer protective diaphragms as previously described.

The invention has been described above in conjunction with embodiments where the outlet pipe 4 and the inserts cooperating therewith possesses a circular cross-section. Of course, the invention is applicable to embodiments having other cross-sections, for example, where the evacuation device has an oval or polygon or other cross-section.

In the preceding description it has been stated that the insert sections 9 and 10 are joined to each other and to the outlet pipe 4 by means of welded joints. It will be appreciated that the connections must ensure that the insert sections are joined with each other and to the outlet section completely tightly. Of course, any tight joint may be used, and the elements may be joined for example, using an adhesive joint or a snap-action joint combined with a sealing agent, or the like.

CLAIMS

1. An evacuation device for a container arranged to enable discharge of the contents of the container upon penetration thereof by a connection device, wherein said evacuation device comprises at least one self-sealing sealing diaphragm of an elastic material, a first space for the accommodation of a connection device during discharge, and a second space, enlarged in relation to the first space, and disposed between the first space and the sealing diaphragm, the sealing diaphragm being arranged to bend inwardly into said second enlarged space under the

influence of pressure applied by the connection device.

2. An evacuation device as claimed in Claim 1, wherein the sealing diaphragm is enclosed between an inner protective diaphragm and an outer protective diaphragm, the inner protecting diaphragm defining said first space from the interior of the container, and the outer protective diaphragm being spaced from the sealing diaphragm and defining therewith a third space having a diameter at least equivalent to the diameter of the first space.

3. An evacuation device as claimed in Claim 1 or 2, further comprising a hollow outlet section in which an insert of a thermoplastics material is disposed, said insert comprising said sealing diaphragm and forming said spaces.

4. An evacuation device as claimed in Claim 3, wherein a region of the limiting walls of the first space is arranged for sealing surface contact with the connection device and has an inner dimension and shape which is matched to the outer dimension and shape of the connection device in the area of sealing surface contact, and wherein said region of the limiting walls of the first space is spaced from outer limiting walls of the outlet section.

5. An evacuation device as claimed in Claim 3 or 4, wherein the insert comprises an inner section and an outer section, and cooperating engagement means are provided on said insert sections and on the sealing diaphragm for retaining the sealing diaphragm.

6. An evacuation device as claimed in Claim 5, wherein the inner insert section forms said first space and said enlarged second space.

7. An evacuation device as claimed in Claim 6, wherein the inner section is formed of first and second cooperating elements the second element being disposed closer to the sealing diaphragm than the first element and forming said first space and said enlarged second space.

8. An evacuation device as claimed in any of Claims 5 to 7, wherein the engagement means are circumferential retaining rings and grooves formed in opposing surfaces of the sealing diaphragm and of the insert sections.

9. An evacuation device as claimed in any of Claims 5 to 8, wherein the outer insert section is formed with said outer protective diaphragm, and the inner insert section is formed with the inner protective diaphragm.

10. An evacuation device as claimed in any of Claims 5 to 9, wherein an inner portion of the inner insert section extends a predetermined amount into the interior of the container.

11. An evacuation device as claimed in any of Claims 3 to 10, wherein the insert is welded into position in the outlet section.

12. An evacuation device as claimed in any of Claims 3 to 11, wherein the outlet section is produced in a single piece with the container.

13. An evacuation device as claimed in any preceding claim, wherein the area of the sealing diaphragm arranged to be penetrated by the connection device is provided with weakened zones wholly or partially extending through the sealing diaphragm.

14. An evacuation device as claimed in Claim 13, wherein said weakened zones comprise a number of intersecting cuts.

15. An evacuation device for a container substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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